DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2003-DT-08

January 15, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael Smith
Director of OP and Clinical Services
Saint Mary's Warrick
1116 Millis Avenue
Boonville, IN 47630

Dear Mr. Smith:

We are writing you because on December 23, 2002, your facility was inspected by a representative of the State of Indiana acting on behalf of the Food & Drug Administration (FDA). The inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The recent inspection at your facility revealed the following Repeat Level 2 finding:

A random review of medical reports revealed that one of six reports reviewed did not have an assessment category. In addition, two of the six medical reports listed a numerical assessment category rather than a descriptive assessment category. These conditions are in violation of Title 21 Code of Federal Regulations § 900.12 (c)(1)(iv) and (v).

The specific violation noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This violation is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the same violation found during your previous inspection.

This condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility and represents a violation of

the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, you should also address the following Level 2 findings that were listed on the inspection report provided at the close of the inspection:

1. There was no documentation of corrective action, following failure of a phantom image score or a phantom background optical density or density difference outside of the allowable regulatory limits, prior to conducting mammography exams. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e)(8).

2. There were no documents available at the time of the inspection to show that Technologist [redacted] met the initial training requirements to conduct mammography exams. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(2)(ii).

It is necessary for you to act on these matters immediately. Please provide to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Repeat Level 2 and Level 2 violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
300 River Place, Suite 5900
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any.

You should also send a copy of your response to the State of Indiana radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

There are many FDA requirements pertaining to mammography. This letter only concerns the findings of your recent inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-393-8156.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)